

REMARKS

Claims 1-3 and 5-12 are pending in the present application. Claims 1, 2, 5 and 8-12 are amended. Claims 4 and 13 are canceled. Support for claims 1 and 9 is found on page 5 at lines 22-27, and on page 9 at lines 6-10, of the specification as filed. Claims 2, 5, and 8, which depend on claim 1 are amended to maintain proper antecedent basis with amended claim 1.

Elections/Restriction

Applicants acknowledge that the restriction requirement is withdrawn.

Rejection under 35 USC § 112, first paragraph

The Examiner rejects claims 1-5 and 8-13 under 35 U.S.C. § 112, first paragraph, for an alleged lack of written description. Applicants respectfully traverse.

The instant claims are drawn to a transposon nucleic acid having two transposon end sequences comprising a genetically engineered translation stop signal in three reading frames wherein one part of said translation stop signal is within a transposon end binding sequence recognized by a transposase, and another part of said translation stop signal is between said transposon end binding sequence and the distal end of said transposon end sequence. The Examiner asserts that the breadth of the claims is not supported or described by the limited species disclosed in the specification. Applicants respectfully disagree.

According to a recent Federal Circuit case, claims should not be invalidated on section 112 grounds simply because the embodiments of the specification do not explicitly cover the full scope of the claim language. “[T]he written description requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way.

As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.” See, e.g. *Falkner-Gunter Falkner v. Inglis* (Fed. Cir. 2006, 05–1324, 17). Therefore, the court stated, that “it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince the skilled artisan that the inventor possessed the invention.” (*Id* at 14.). Based on the reasoning in *Falkner*, the instant claims comply with the written description requirement because the skilled artisan can envision the genus of the inventive transposon nucleic acids.

First, Applicants wish to refer the Examiner to the scientific article of Mahillon and Chandler, which shows the level of knowledge in the field of transposon technology. (*Mahillon and Chandler, Microbiology and Molecular Biology Reviews*, 62, 3, 725-774 (1998), excerpt attached as Exhibit 1.). This article discloses an exhaustive list of transposon families (particularly insertion sequences). Thus, the skilled artisan can envision a vast number of transposon sequences because these were known in the art before the filing date of the instant application.

Second, the transposon end structure is basically universal in different transposon families. As seen in Figure 1, and as described on page 727, right column, first paragraph, of the Mahillon and Chandler reference, the tips of the transposon elements (referred to as transposon end sequences in the present specification, at page 5, lines 18-20) include inverted repeats, between which is a single open reading frame encoding transposase. “Transposase” refers to an enzyme that mediates transposition. The inverted repeats typically include two functional domains. Domain I represents the terminal base pairs at the very tip of the element whose recognition is required for transposase-mediated cleavage. Domain II represents the base pairs necessary for sequence-specific recognition and binding by the transposase. In the present specification, Domain II is referred to as a “transposon end binding sequence”, see page 5, at lines 22-24. Thus, the skilled artisan can envision a vast number of transposon end sequences and recognize the particular nucleic acids within an end sequence, which encompass Domain II, as well as the specific nucleic acids within Domain I.

In Figure 2 of the instant application, these domains are easily seen. Domain I of the Mu transposon contains the sequence TGAAG, proximal to the 3' end cleavage point of the transposon. (See, the upper strand of Cat-Mu transposon in Figure 2). The R1 and R2 sequences of the Mu transposon represent Domain II. The teaching of the invention can be seen in the Cat-Mu(Stopx3) transposon of Figure 2. In order to engineer the Mu transposon so that the stop codons are as close as possible to the tip of the transposon, two base pairs in Domain I (*i.e.* the TGAAG sequence) and five base pairs in Domain II (*i.e.* Mu-R1 sequence) are altered (the sites of modification are shown by asterisk in Figure 2). Thus, the present invention shows, for the first time, that Domain I and Domain II of a transposon end can be mutated, while still retaining the ability to transpose. The same result is also shown with the Tn7 transposon in Example 4 of the present application.

Nevertheless, the Examiner alleges that the invention is not adequately described because the modification within the transposon end sequence, such as the Mu R-end sequence, could be anywhere within the end of the transposon. This allegation is not true. The present specification particularly discloses that the effect of the invention is obtained by engineering the transposon end so that the three stop signals are as near as possible to the nucleic acids of the transposon end sequence which flank a target sequence after the transposon is incorporated into a target (*i.e.* the stop signals are situated at the very tip of the transposon end; see, page 9, lines 6-10 of the specification). This location is exemplified by the Cat-Mu(Stopx3) transposon of Figure 2 in which the TGAAG sequence (Domain I) and the edge of the R1 sequence (Domain II) are modified. Additionally, the subject matter of claim 1 recites that the location of the stop signal is partly within a transposon binding end sequence and partly between the transposon binding end sequence and the distal end of the transposon end sequence. Therefore, the modification of the transposon is not 'anywhere within the end of the transposon' as the Office Action states.

Thus, a person of skill in the art is given adequate description and guidance to envision the inventive transposon nucleic acids. The skilled artisan is already aware of vast numbers of transposon sequences. Likewise, the skilled artisan is aware of the nucleic acid sequences that make up the transposase end sequences, as well as the transposon end binding sequences of any given transposon. Therefore, a skilled artisan can envision the nucleic acids wherein one part of a translation stop signal is within a transposon end binding sequence recognized by a transposase and another part of the translation stop signal is between the transposon end binding sequence and the distal end of the transposon end sequence. Therefore, the skilled artisan, using the description in the present specification, can envision where, in any particular transposon end sequence, modification can occur to obtain a translation stop signal in three reading frames, according to the present invention. Thus, claim 1 complies with the written description requirement. Claim 2-5 and 8-13, which also incorporate the subject matter of claim 1, likewise, comply with the written description requirement for the above-stated reasons. Accordingly, Applicants respectfully request this rejection be reconsidered and withdrawn.

The favorable actions of withdrawal of all of the standing objections and rejections and passage of the application to allowance are respectfully requested.

Should there be any minor issues preventing allowance of the application that can be addressed by a telephone conversation, the Examiner is invited to call the undersigned at 703-205-8020 to discuss the matter.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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